BEFORE THE
SCIENCE SUBCOMMITTEE OF THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: JULY 22, 2022
11 A.M.

REPORTER: BETH C. DRAIN, CA CSR
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JULY 22, 2022; 11 A.M.

CHAIRMAN GOLDSTEIN: ALL RIGHT. LET'S DO IT. SO LET ME CALL US TO ORDER. AND AS I REMEMBER THE ORDER OF THE --

MS. BONNEVILLE: REALLY QUICKLY, LARRY, LET'S JUST GET THE YOUTUBE STARTED. WE'VE GOT YOU-TUBE GOING, SO I WILL CALL ROLL.

LOREN ALVING.

DR. ALVING: HERE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: HERE.

MS. BONNEVILLE: LARRY GOLDSTEIN.

CHAIRMAN GOLDSTEIN: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: MORNING.

MS. BONNEVILLE: JONATHAN THOMAS.

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CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: PRESENT.

MS. BONNEVILLE: KAROL WATSON. KEITH YAMAMOTO.

DR. YAMAMOTO: HERE.

MS. BONNEVILLE: AND THEN I WOULD NOTE THAT DEBORAH DEAS AND PAT LEVITT ARE NOT PRESENT. SO WE CAN START.

CHAIRMAN GOLDSTEIN: OKAY. GREAT. FIRST ORDER OF BUSINESS IS CHANGES TO THE CLINICAL PLAN ADVISORY COMMENTS. I BELIEVE ABLA CREASEY IS DOING THAT ONE; IS THAT CORRECT?

MS. BONNEVILLE: ABLA CREASEY IS DOING THAT, YES.

DR. CREASEY: YES, GOOD MORNING. I'LL SEE IF I CAN SHOW MY SLIDES. OKAY.

GOOD MORNING, EVERYONE, DEAR MEMBERS OF THE SCIENCE SUBCOMMITTEE. SO I AM THE HEAD OF THERAPEUTICS DEVELOPMENT AT CIRM, AND I'M BEING TODAY GIL SINCE HE IS ON VACATION THIS WEEK AND HE USUALLY GIVES THESE PRESENTATIONS. SO I AM PRESENTING THE PROPOSED REVISIONS TO THE CLIN2 CONCEPT.

THE PROPOSED REVISION TO CLIN2 CONCEPT IS

AS FOLLOWS. THERAPEUTIC CANDIDATES CURRENTLY ALLOW CLINICAL TRIAL STUDIES WITH A CANDIDATE THAT'S EITHER STEM CELL THERAPY OR GENETIC THERAPY PHASE I, II, OR III CLINICAL TRIALS WHILE SMALL MOLECULE OR BIOLOGICS INVOLVE STEM CELLS, PHASE I CLINICAL TRIALS ONLY.

WE PROPOSE TO UNIFY ELIGIBILITY TO ALLOW ALL THREE CATEGORIES TO QUALIFY FOR A PHASE I, II, OR III TRIALS. THIS ACTION ALLOWS FOR CONSISTENT ELIGIBILITY REQUIREMENT ACROSS ALL CLINICAL APPLICATIONS AND PROVIDES THE POSSIBILITY OF ONGOING CIRM SUPPORT FOR SMALL MOLECULES AND BIOLOGICS THAT ARE READY TO ADVANCE TO LATE STAGE CLINICAL DEVELOPMENT.

THE EXISTING ELIGIBILITY LANGUAGE WOULD THEN BE EXTENDED TO PHASE II AND PHASE III CLINICAL TRIALS. THIS IS WHAT YOU SEE ON THE SLIDE. A SMALL MOLECULE OR A BIOLOGIC THAT ACTS ON OR IS DEPENDENT ON ENDOGENOUS HUMAN STEM CELLS FOR ITS THERAPEUTIC EFFECT, THAT IS DEPENDENT ON TARGETING HUMAN CANCER STEM CELLS FOR ITS THERAPEUTIC EFFECT, THAT MODIFIES A STEM CELL THERAPY, OR WHERE A HUMAN STEM CELL IS NECESSARY TO MANUFACTURE THE THERAPY; SUCH AS, EXTRACELLULAR VESICLES.

THERE ARE ADDITIONAL MINOR REVISIONS THAT

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ARE BEING PROPOSED MAINLY FOR CLARIFICATION SUCH AS GENE THERAPY TO GENETIC THERAPY. THERE ARE ALSO A FEW INSTANCES WHERE THE UPDATE WAS MISSED IN THE LAST ROUND OF CHANGES TO ALIGN WITH ADOPTED DEFINITION OF GENETIC THERAPY. CLARIFICATION THAT FEASIBILITY TRIALS FOR MEDICAL DEVICES ARE INCLUDED WITHIN THE REQUIREMENTS FOR AWARD AMOUNT LIMITS AND COFUNDING AMOUNTS.

SO THE ACTION REQUESTED IS TO PLEASE APPROVE OF THE PROPOSED AMENDMENTS TO THE CLIN2 CONCEPT PLAN. WITH THAT I'LL STOP.

CHAIRMAN GOLDSTEIN: OKAY. QUESTIONS FOR ABLA OR OTHER CIRM STAFF REGARDING THIS PROPOSAL?

CHAIRMAN THOMAS: LARRY, WHY DON'T WE GET A MOTION ON THE TABLE. I'LL MOVE.

CHAIRMAN GOLDSTEIN: OKAY. THANK YOU, J.T. SECOND?

DR. HIGGINS: SECOND.

CHAIRMAN GOLDSTEIN: OKAY. NOW THEN, DISCUSSION OR QUESTIONS PLEASE. LET'S SEE. JUDY, DID YOU JUST WAVE YOUR HAND?

MS. BONNEVILLE: DR. MELMED HAD HIS HAND RAISED.

DR. MELMED: OBVIOUSLY THIS SOUNDS VERY, VERY IMPORTANT AND HELPFUL TO PROCEED WITH THIS.

I'M JUST CURIOUS, BEING AN OLD VETERAN ON THIS COMMITTEE, WHAT WAS OUR ORIGINAL RATIONALE FOR SPLITTING IT UP? J.T., DO YOU REMEMBER, OR WAS IT EVEN BEFORE YOUR TIME? WHY WAS THIS DISTINCTION MADE? WAS THERE A REASON FOR IT WHICH WE'RE CURRENTLY UNAWARE OF?

DR. CREASEY: CAN I ANSWER THAT QUESTION?

CHAIRMAN THOMAS: OF COURSE, ABLA, PLEASE.

DR. CREASEY: AGAIN, AS A NEWCOMER TO CIRM AND HAVING WORKED FOR PHARMA, I THINK THE IDEA WAS BEYOND PHASE I, IT'S LIKELY THAT THE PHARMA AND BIOTECH COMPANIES WILL INVEST IN SUCH A PROGRAM AND PROBABLY WAS ONE OF THE REASONS, BUT MAYBE J.T. HAS OTHERS.

CHAIRMAN THOMAS: ONE OF THE BIG DRIVERS, SHLOMO, WAS WHEN WE WERE RUNNING OUT OF FUNDS A COUPLE YEARS PRIOR TO THE PASSAGE OF PROP 14, THERE WAS DISCUSSION ABOUT CUTTING BACK ON CERTAIN THINGS THAT WERE ELIGIBLE FOR FUNDING, AND THIS WAS ONE OF THOSE. AND SO THE IDEA HERE, I THINK, IS TO REINSTATE IT BECAUSE ALL OF THE PHASE II AND PHASE III WORK, IT ALL STILL MUST HAVE TO DO IN SOME CAPACITY WITH STEM CELLS ONE WAY OR ANOTHER, WHETHER IT'S SMALL MOLECULES, BIOLOGICS, OR ANYTHING ELSE.

SO KEEPING THAT REQUIREMENT IN PLACE AND

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NOW HAVING THE LUXURY, COURTESY OF THE VOTERS OF HAVING THE FUNDING AVAILABLE, I THINK IT WAS THE TEAM'S VIEW THAT IT'S TIME TO EXPAND THE DEFINITION TO INCLUDE EVERYTHING IN PHASE II AND PHASE III AS WELL.

DR. CREASEY: AND TOWARDS THE END OF PROPOSITION 71, WE HAD LIMITED FUNDS. SO WE HAD TO PRIORITIZE. AND NOW THAT WE HAVE THE PROPOSITION 14, THE FUNDS COULD BE MADE AVAILABLE IF YOU DECIDE TO DO THAT.

MS. BONNEVILLE: LARRY, MARIA HAS HER HAND RAISED.

CHAIRMAN GOLDSTEIN: MARIA MILLAN PLEASE.

DR. MILLAN: ABSOLUTELY. I JUST WANTED TO MAYBE GIVE SOME CONTEXT AS TO WHY WE'RE BRINGING IT TO YOUR ATTENTION NOW. IT REALLY CAME TO OUR ATTENTION THAT, ESPECIALLY WITH THE MARKET AS IT IS IN TERMS OF INVESTMENT INTO EARLY STAGE PROGRAMS, AND SOME OF THE PROGRAMS WE HAD FUNDED THROUGH THE EARLY STAGES INTO PHASE I THAT SHOWED SOME PROMISE, INCLUDING COMBINATION THERAPIES WHERE SMALL MOLECULES OR BIOLOGICS ARE NEEDED FOR THE SUCCESS OF CELL TRANSPLANT, LIKE A NONTOXIC CONDITIONING REGIMEN, FOR INSTANCE, OR SOME OF THE NOVEL SMALL MOLECULES AND BIOLOGICS THAT TARGETED A STEM CELL

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REGENERATIVE MEDICINE MECHANISM OF ACTION THAT IS NOT NECESSARILY OUT IN THE STANDARD DEVELOPMENT PATH, OR THE TYPES OF APPROACHES THAT ADDRESS RARE DISEASE, ULTRA RARE DISEASE WHICH CURRENTLY RIGHT NOW ARE BEING TAKEN CARE OF BY ACADEMIA, THESE ARE THE TYPES OF PROGRAMS THAT ARE UNIQUELY THE TYPES OF PROGRAMS THAT WOULDN'T HAVE EVEN GOTTEN THIS FAR WERE IT NOT FOR CIRM.

AND THEY ALSO WOULD HAVE HAD A HARD TIME GETTING INDUSTRY SUPPORT EVEN UNDER THE BEST CIRCUMSTANCE, BUT ESPECIALLY WITH THE MARKET WHERE IT IS AND INVESTMENTS OR ACCESS TO CAPITAL IS VERY CHALLENGING, VERY COMPETITIVE RIGHT NOW. WE WANTED TO MAKE SURE THAT PROGRAMS THAT WE HAD INVESTED IN AND ESPECIALLY THOSE THAT COULD BE VERY IMPACTFUL TO THE MISSION AND TO THE PATIENTS AND TO THE TYPES OF TECHNOLOGIES WE ARE BRINGING FORWARD, THAT WE HAVE A WAY TO TAKE CARE OF THOSE PROGRAMS.

SO THAT'S THE CONTEXT OF WHY TODAY IN ADDITION TO THE FACT THAT WE ALSO HAVE, AS J.T. AND ABLA HAD POINTED OUT, WE HAVE THE ABILITY TO SUPPORT IT THROUGH THE RENEWED FUNDING.

DR. MELMED: I WAS JUST CONCERNED THERE WAS A POLICY. BUT BASED ON WHAT YOU SAID NOW, AND I APPLAUD THIS APPROACH AND IT'S GREAT THAT WE ARE

DOING THIS, BUT WE HAVE TO REALIZE WE ARE IN FOR HUNDREDS OF MILLIONS OF DOLLARS. I MEAN A SUCCESSFUL PHASE III TRIAL, IF IT'S WELL-DESIGNED, IS EXTREMELY EXPENSIVE.

DR. CREASEY: OUR FUNDING WILL CONTINUE TO BE THE SAME, MEANING WE WILL, FOR EXAMPLE, A PHASE III TRIAL WILL GET $15 MILLION FROM US, AND THE REST WILL BE THROUGH COFUNDING AND OTHER RESOURCES THE PARTY WOULD HAVE TO IDENTIFY.

THE KEY HERE ALSO IS PLEASE REMEMBER THAT THERAPEUTICS, SMALL MOLECULES, AND BIOLOGICS WILL HAVE TO HAVE SOME RELATIONSHIP INVOLVEMENT WITH STEM CELLS. SO THOSE ARE THE ONES WE ARE ADVOCATING FOR.

DR. MELMED: THANK YOU.

CHAIRMAN GOLDSTEIN: OTHER QUESTIONS FROM MEMBERS OF THE SUBCOMMITTEE? OKAY. HEARING NONE, LET'S SEE, MARIA, IS IT TIME FOR PUBLIC COMMENT?

MS. BONNEVILLE: IT IS AND I DO NOT SEE ANY HANDS RAISED FOR PUBLIC COMMENT.

CHAIRMAN GOLDSTEIN: OKAY. SO I SUGGEST -- LET'S SEE. DO WE HAVE TO HAVE ANOTHER MOTION TO VOTE OR WE GO STRAIGHT TO THE VOTE, MARIA?

MS. BONNEVILLE: WE CAN GO STRAIGHT TO THE VOTE.

CHAIRMAN GOLDSTEIN: OKAY. CALL THE

QUESTION AND VOTE PLEASE.

MS. BONNEVILLE: LOREN ALVING.

DR. ALVING: YES.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: YES.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: LARRY GOLDSTEIN.

CHAIRMAN GOLDSTEIN: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: ENTHUSIASTIC YES.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: KAROL WATSON.

DR. WATSON: YES.

MS. BONNEVILLE: KEITH YAMAMOTO.

DR. YAMAMOTO: YES.

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MS. BONNEVILLE: THE MOTION CARRIES.

CHAIRMAN GOLDSTEIN: OKAY. THANK YOU, EVERYBODY.

NEXT UP IS SHYAM TELLING US ABOUT A PROPOSED CONCEPT FOR A NETWORK OF CELL AND GENE MANUFACTURING FACILITIES. SHYAM, TAKE IT AWAY.

DR. PATEL: THANK YOU, DR. GOLDSTEIN. SO I'M GOING TO PUT UP MY PRESENTATION. ONE SECOND PLEASE. JUST TRANSFERRED TO A NEW LAPTOP. I'M HAVING SOME PERMISSION ISSUES. SO I'M TRYING TO WORK IT OUT.

MS. BONNEVILLE: SHYAM, DO YOU WANT US TO SHARE THE SCREEN WITH WHAT'S POSTED ONLINE? YOU JUST LET US KNOW.

DR. PATEL: I GUESS I COULD GO WITH THAT BECAUSE THIS IS NOT WORKING AT THE MOMENT.

MS. BONNEVILLE: MARIANNE, DO YOU WANT TO SHARE THE DOCUMENT THAT SHYAM SENT YOU THAT WE POSTED?

DR. PATEL: THANK YOU, MARIANNE. AND I'LL JUST LET YOU KNOW WHEN TO PROGRESS SLIDES. SO I APOLOGIZE FOR THAT.

AND TODAY I WANT TO PRESENT A CONCEPT PLAN FOR A MANUFACTURING NETWORK IN THE STATE OF CALIFORNIA FOR CELL AND GENE THERAPY MANUFACTURING.

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I'M GOING TO TELL YOU IN ADVANCE THAT THERE WERE SUPPOSED TO BE QUITE A FEW ANIMATIONS IN THE SLIDES, SO I'LL DO MY BEST HERE WITH RESPECT TO WALKING YOU THROUGH A LOT OF TEXT. SO JUST BEAR WITH ME PLEASE.

SO AS WE ALWAYS START OFF WITH THE MISSION STATEMENT, ACCELERATING WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD. SO NEXT SLIDE PLEASE.

LATE LAST YEAR THE BOARD HAD APPROVED OUR FIVE-YEAR STRATEGIC PLAN, AND WITHIN THAT PLAN THERE WERE THREE MAJOR THEMES. AND THIS PARTICULAR CONCEPT PLAN ADDRESSES ONE OF THE OBJECTIVES IN THE DELIVERY OF REAL WORLD SOLUTIONS THEME, WHICH WAS CREATING A MANUFACTURING PARTNERSHIP NETWORK, BUT IT ALSO TOUCHES ON THE COMPETENCY HUBS AND THE WORKFORCE DEVELOPMENT OBJECTIVES OF THE OTHER TWO THEMES. AND I'LL BE WALKING THROUGH THE PRESENTATION, THE CONCEPT PLAN, OVER THE NEXT FEW SLIDES.

BEFORE I DO THAT, I WANT TO SET THE BACKGROUND IN TERMS OF THE CURRENT BOTTLENECKS IN MANUFACTURING. NEXT SLIDE PLEASE, MARIANNE.

SO WE ARE ALL AWARE THAT THERE'S BEEN A RAPID GROWTH IN REGENERATIVE MEDICINE, PARTICULARLY

IN CELL AND GENE THERAPIES, AND NOW THEY'RE RAPIDLY PROGRESSING THROUGH CLINICAL TRIALS IN MANY INSTANCES. AND THAT RAPID PROGRESSION OF THESE THERAPEUTIC CANDIDATES OFTEN CREATES A BURDEN ON MANUFACTURING WHERE SOME OF THE BOTTLENECKS IN MANUFACTURING DEVELOPMENT CAN ACTUALLY SLOW DOWN THE OVERALL DEVELOPMENT OF THE THERAPIES THEMSELVES.

AND SO THERE ARE A FEW INFRASTRUCTURE BOTTLENECKS AS WELL AS SOME TECHNICAL BOTTLENECKS AND RESOURCE BOTTLENECKS THAT ARE ADDRESSED HERE. SO FIRST AND FOREMOST, THE ACADEMIC INSTITUTIONS ARE THE CENTER OF TECHNOLOGY INNOVATION, INITIAL PROCESS DEVELOPMENT, AND GMP MANUFACTURING, BUT THEY DON'T HAVE SUFFICIENT CAPACITY, RESOURCES, OR PROCESSES FOR LATE STAGE MANUFACTURING. AND OFTEN THIS IS BY DESIGN.

ON THE INDUSTRY SIDE, THERE ARE INDUSTRY CONTRACT DEVELOPMENT AND MANUFACTURING ORGANIZATIONS THAT SPECIALIZE IN MANUFACTURING FOR SPONSORS OR IN-HOUSE MANUFACTURING OPERATIONS OF COMPANIES OF ALL SIZES, AND THESE ARE BEST POSITIONED TO INDUSTRIALIZE MANUFACTURING PROCESSES FOR LATE STAGE CLINICAL TRIALS AND COMMERCIALIZATION, BUT THEY DON'T ALWAYS HAVE THE EXPERTISE IN EMERGING TECHNOLOGY PLATFORMS THAT ARISE FROM ACADEMIA, WHICH

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IS OFTEN THE CASE FOR CELL AND GENE THERAPIES IN PARTICULAR.

ON TOP OF THAT, THERE'S TECHNICAL BOTTLENECKS THAT ARISE FROM THE COMPLEXITY OF THE PRODUCTS AND PROCESSES THEMSELVES. THESE ARE LIVING PRODUCTS IN MANY CASES, AND THEY HAVE COMPLICATED MULTISTEP PROCESSES.

AND THEN, LASTLY, BECAUSE OF THE RAPID GROWTH IN THE INDUSTRY, THERE'S AN EVER-GROWING DEMAND FOR TRAINED MANUFACTURING AND QUALITY WORKFORCE. AND SOME OF THESE AREAS ARE BEING ADDRESSED BY THE CONCEPT PLAN BEING PRESENTED TO YOU TODAY.

FIRST AND FOREMOST, I WANT TO LAY OUT THE LANDSCAPE. SO NEXT SLIDE PLEASE, MARIANNE. SO IN CALIFORNIA WE BENEFIT FROM HAVING A VERY RICH NETWORK OF ACADEMIC GMP MANUFACTURING FACILITIES. IN FACT, A MAJORITY OF CIRM-FUNDED PROJECTS UTILIZE THESE GMP MANUFACTURING FACILITIES FOR THEIR CELL AND GENE THERAPY PROCESS DEVELOPMENT. THESE INCLUDE FACILITIES THAT HAVE BEEN AROUND FOR A LONG TIME, LIKE THE UC DAVIS, UC SAN DIEGO, AND CITY OF HOPE, AS WELL AS RECENT ONES THAT HAVE JUST OPENED; FOR EXAMPLE, CEDARS-SINAI, UC IRVINE, AND USC.

ON THE INDUSTRY SIDE, THERE'S BEEN A

GROWING PRESENCE OF CONTRACT DEVELOPMENT AND MANUFACTURING ORGANIZATIONS. THESE EITHER PROVIDE FEE FOR SERVICE OR HAVE PARTNERSHIP MODELS. THERE'S BEEN A RAPID GROWTH OF THESE ESPECIALLY IN THE LAST COUPLE YEARS, AND PRIOR TO THAT THERE REALLY WEREN'T THAT MANY CDMO'S IN THE STATE OF CALIFORNIA.

IN ADDITION TO THAT, SEVERAL BIOPHARMA COMPANIES ARE ALSO MANUFACTURING IN CALIFORNIA FOR THEIR PARTNER PROJECTS. AND TWO OF OUR INDUSTRY ALLIANCE PROGRAM PARTNERS, BAYER AND NOVO AND NORDISK, BOTH HAVE THIS CAPACITY AT THEIR BAY AREA FACILITIES AT THE MOMENT FOR PARTNER PROJECTS.

NEXT SLIDE PLEASE.

SO GIVEN THAT LANDSCAPE, IN THE STRATEGIC PLAN WE HAD PROPOSED TO CREATE A MANUFACTURING NETWORK THAT LINKS THE ADVANTAGES OF THE ACADEMIC GMP FACILITIES WITH THE ADVANTAGES OF THE INDUSTRY PARTNERS ALL IN SERVICE OF THE THREE CORE GOALS. THE FIRST WOULD BE TO ACCELERATE AND DERISK THE PATHWAY TO COMMERCIALIZATION FOR CIRM-FUNDED CELL AND GENE THERAPY PROJECTS. SECOND, TO ADVANCE STANDARDS AND QUALITY-BY-DESIGN INDUSTRY STANDARDS THAT WOULD HELP INDUSTRIALIZE THE PROCESS AND CREATE MORE CONSISTENCY AND HIGHER QUALITY PRODUCTS. AND, LASTLY, TO BUILD THE MANUFACTURING LEADERSHIP AND

WORKFORCE IN THE STATE OF CALIFORNIA.

SO NEXT SLIDE PLEASE, MARIANNE. WHAT COULD BE SOME OF THE POTENTIAL FUNCTIONS OF THE MANUFACTURING NETWORK TO ADDRESS THOSE THREE GOALS, AND THOSE ARE DESCRIBED IN THIS SLIDE HERE. SO FIRST AND FOREMOST, WORLD CLASS EXPERTISE ACROSS THE FULL RANGE OF MANUFACTURING AND ANALYTICAL TECHNOLOGY PLATFORMS FROM STEM CELLS TO GENE EDITING, FOR EXAMPLE; TO SUPPORT THE MANUFACTURING OF THERAPIES FOR RARE, ULTRA RARE DISEASES. THESE ARE PLATFORM-BASED APPROACHES THAT COULD POTENTIALLY DEVELOP AND MANUFACTURE VARYING CELL AND GENE THERAPY PRODUCTS FOR A LARGE NUMBER OF ULTRA RARE DISEASES. TO ACCELERATE AND DERISK LATE STAGE AND COMMERCIAL MANUFACTURING OF THERAPIES. THIS IS PARTICULARLY IMPORTANT AS THE FIELD MATURES AND AS DOES CIRM'S PORTFOLIO AND THE NEED FOR LATE STATE MANUFACTURING FOR LARGER CLINICAL TRIALS AS WELL AS COMMERCIAL MANUFACTURING FOR APPROVED THERAPIES INCREASING IN THE STATE OF CALIFORNIA.

TO ESTABLISH CENTERS FOR QUALITY OR ACCREDITATION OF MANUFACTURING FACILITIES. THIS IS EQUALLY IMPORTANT AS THE FIELD MATURES.

AND LASTLY, TO BUILD INCLUSIVE WORKFORCE ENTRY AND ADVANCEMENT OPPORTUNITIES IN TECHNICAL AND

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LEADERSHIP CAREER PATHWAYS THAT PARTNER WITH OUR EDUC PROGRAMS AS WELL AS INDUSTRY STAKEHOLDERS RANGING FROM COMMUNITY COLLEGES TO BIOTECH COMPANIES TO THE CONTRACT MANUFACTURERS IN THE STATE AS I LISTED PREVIOUSLY.

SO THE NEXT FEW SLIDES I'M GOING TO WALK YOU THROUGH THE CONCEPT PLAN. THIS IS A BROAD OVERVIEW FIRST AND THEN POTENTIAL ACTIVITIES. SO THIS IS A BIPHASIC FUNDING OPPORTUNITY THAT WE'RE PRESENTING IN THIS CONCEPT PLAN COMPOSED OF TWO DISTINCT, BUT INTERRELATED RFA'S. SO THE FIRST PHASE OF THE RFA WOULD BE TO HAVE A PROGRAM BUDGET OF $20 MILLION. THESE WOULD BE MAX TWO YEAR, MAX $2 MILLION AWARDS, AND THE APPLICANT AND AWARDEE WOULD BE ACADEMIC GMP MANUFACTURING FACILITIES WITH THE INTENT THAT THESE PHASE I AWARDS ARE FOCUSED ON INDIVIDUAL FACILITY ENHANCEMENTS AT THOSE FACILITIES THEMSELVES.

THE PHASE II RFA WOULD HAVE A PROGRAM BUDGET OF $60 MILLION WITH A MAX AWARD DURATION OF FIVE YEARS AND A MAX AWARD AMOUNT OF $5 MILLION. HERE THE APPLICANT GMP FACILITY WOULD BE APPLYING TO PROPOSE COLLABORATIONS WHICH IN TURN WOULD ALLOW FOR SCALING OF THE ENHANCEMENTS AND SPECIALIZATIONS AND TRAINING PROGRAMS THAT THEY HAD MADE PROGRESS TOWARD

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IN THE PHASE I APPLICATION. SO BASICALLY THE PHASE II IS SCALING UP IN COLLABORATION WITH OTHERS OF THE ACTIVITIES THAT THEY HAD DONE IN PHASE I.

SO IN ADDITION TO THE AWARDS THEMSELVES, CIRM WOULD COORDINATE A STEERING COMMITTEE OF AWARDEES AND EXTERNAL PARTICIPANTS. THIS STEERING COMMITTEE WOULD PLAY AN IMPORTANT ROLE WHICH WILL ACT AS THE GLUE BETWEEN THE AWARDEES THEMSELVES AS WELL AS TO FACILITATE THE TRANSITION FROM PHASE I TO PHASE II.

SO IN THE NEXT FEW SLIDES, I'M GOING TO WALK THROUGH POTENTIAL ACTIVITIES FOR PHASE I AND PHASE II, HOW PHASE I AND PHASE II INTERPLAY WITH EACH OTHER, AS WELL AS WHAT THE STEERING COMMITTEE ITSELF CAN BE DOING. BUT I DO WANT TO NOTE THAT BOTH IN THE PHASE I AND PHASE II RFA'S, THE ENCOURAGEMENT EXPECTATION IS THAT THE AWARDEES ARE WORKING IN COLLABORATION WITH OTHER ACADEMIC FACILITIES AS WELL AS THE INDUSTRY STAKEHOLDERS IN THE STATE OF CALIFORNIA.

SO THIS IS A VERY BUSY SLIDE BECAUSE IT WAS MEANT TO PROGRESS THROUGH SOME OF THESE THINGS, SO JUST BEAR WITH ME AS I WALK THROUGH THIS. SO THE POTENTIAL AWARD ACTIVITIES THAT WE ENVISION FOR BOTH PHASE I AND PHASE II, AGAIN, THESE ARE MEANT TO BE

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EXAMPLES AS INFORMATIVE INFORMATION ONLY AND NOT MEANT TO BE LIMITING IN ANY WAY FOR THE EVENTUAL RFA AND AWARDS.

WE ARE BUCKETING THE THREE MAJOR CATEGORIES. SO FIRST AND FOREMOST IS TO DERISK AND ACCELERATE MANUFACTURING AS I'VE BEEN CONSTANTLY TALKING ABOUT THROUGHOUT THIS PRESENTATION. AND SO HERE POTENTIAL ACTIVITIES COULD INVOLVE QUALITY DRIVEN OPERATIONAL ENHANCEMENTS THAT DERISK PROCESS DEVELOPMENT, GMP MANUFACTURING, AND TECHNOLOGY TRANSFER FROM PRE-IND THROUGH TO COMMERCIALIZATION. IT COULD INVOLVE ACTIVELY MITIGATING CAPACITY AND EXPERTISE GAPS BY COORDINATING PROJECT EXECUTION ACROSS THE NETWORK. OFTENTIMES SOME PROJECTS MAY HAVE LEAD TIMES OF A COUPLE YEARS, OR SOME FACILITIES MAY NOT HAVE THE EXPERTISE IN A PARTICULAR AREA, BUT THEY COULD COORDINATE WITH OTHERS TO SUPPORT THOSE PROJECTS.

WE WOULD ENCOURAGE APPLICANTS TO PROPOSE SPECIALIZATION IN PARTICULAR AREAS. SO THESE COULD BE BUILDING NETWORKWIDE SPECIALIZATION IN AREAS SUCH AS TECHNOLOGY PLATFORMS, CRISPR, FOR EXAMPLE, ANALYTICAL METHODS, PIONEERING QUALITY-BY-DESIGN IMPLEMENTATION, AUTOMATION OF MANUFACTURING, OR HAVING RARE DISEASE MANUFACTURING PLATFORMS.

THE LAST THING ON THE WORKFORCE DEVELOPMENT SIDE, THEY WOULD BE PROPOSING DEVELOPMENT AND IMPLEMENTATION OF TRAINING PROGRAMS FOR TECHNICAL POSITIONS THAT COULD INVOLVE INTERNSHIPS AND CERTIFICATION PROGRAMS, AS WELL AS MENTORING PROGRAMS FOR LEADERSHIP POSITIONS. AND THESE WILL BE IN PARTNERSHIP WITH OUR EDUC PROGRAMS, WHICH COULD BE THE FEEDER FOR A LOT OF THESE POSITIONS, AS WELL AS INDUSTRY STAKEHOLDERS WHICH COULD BE BOTH THE FEEDER AND DESTINATION FOR SOME OF THE TRAINEES.

SO AS I MENTIONED PREVIOUSLY, THE PHASE I AWARDS WOULD FOCUS ON INITIAL PROGRESS IN THESE AREAS AT THE ACADEMIC FACILITIES WHILE PHASE II WOULD BE HOW TO SCALE THESE ACROSS THE NETWORK. AND SO WHAT I'M GOING TO DO IS TO ILLUSTRATE THE INTERPLAY BETWEEN PHASE I AND PHASE II IS TO WALK YOU THROUGH POTENTIAL ACTIVITIES THAT COULD BE DONE IN PHASE I AND PHASE II FOR THAT FIRST EXAMPLE WHICH IS OUTLINED IN THAT BOX AROUND DERISKING MANUFACTURING. NEXT SLIDE PLEASE, MARIANNE.

SO HERE ON THE PHASE I SIDE, TO DERISK MANUFACTURING, THOSE INDIVIDUAL AWARDEES COULD BE MAKING QUALITY SYSTEM IMPROVEMENTS AT THEIR FACILITIES. THEY COULD BE IMPLEMENTING

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QUALITY-BY-DESIGN PRINCIPLES. AND THEY COULD BE HIRING AND TRAINING NEW STAFF AROUND THAT TO BASICALLY BOLSTER THEIR OPERATIONS ALL WITH THE INTENT OF BEING ABLE TO BETTER SUPPORT PROCESS DEVELOPMENT, BETTER TECH TRANSFER PROJECTS INTO THEIR FACILITIES FOR EARLY STAGE MANUFACTURING, AND THEN TO BETTER TRANSITION THOSE PROJECTS OUT OF THEIR FACILITIES FOR LATE STAGE MANUFACTURING WHEN THE NEED ARISES FOR THOSE PROJECTS FOR LATER STAGE CLINICAL TRIALS AS WELL AS COMMERCIAL MANUFACTURING.

SO POTENTIAL OUTCOME METRIC FOR A PHASE I AWARD FOR THIS PARTICULAR SET OF ACTIVITIES COULD BE HOW WELL DID THOSE QUALITY SYSTEM IMPROVEMENTS IMPACT PROJECT EXECUTION COMPARED TO HISTORICAL PERFORMANCE AT THOSE FACILITIES OR GLOBALLY? AND THEN TO TIE THEM TO THE PHASE II, BASED ON KNOWING WHICH QUALITY-DRIVEN IMPROVEMENTS WERE SUCCESSFUL, THOSE COULD BE SCALED ACROSS THE PARTICIPANT ORGANIZATIONS. AND THEN THEY CAN ALSO OPERATIONALIZE PARTNERSHIPS TO EFFECTIVELY TRANSITION PROJECTS FOR LATE STAGE COMMERCIAL MANUFACTURING. SO BASED ON WHAT WERE THE BEST PRACTICES IN TERMS OF COORDINATION BETWEEN ACADEMIC FACILITIES AND INDUSTRY PARTNERS TO FACILITATE PROGRESSION OF PROJECTS FROM INITIAL MANUFACTURING

TO LATE STAGE MANUFACTURING, THOSE COULD BE OPERATIONALIZED MORE FULLY IN THE PHASE II AWARDS.

SO POTENTIAL OUTCOME METRICS FOR PHASE II AWARDS COULD BE WHAT IS THE SUCCESS RATE OF TRANSITIONING PROJECTS TO LATE STAGE MANUFACTURING, AS WELL AS HOW WELL WERE THE QUALITY STANDARDS, PROTOCOLS, AND BEST PRACTICES APPLIED ACROSS THE NETWORK?

SO TO GO BACK TO THE OTHER TWO CATEGORIES AND PROPOSE SOME OUTCOME METRICS FOR THOSE. SO WITH RESPECT TO SPECIALIZATION AREAS, IN PHASE I THE AWARDEES COULD DEMONSTRATE COMPETENCIES IN SPECIALIZATION AREAS BY EXECUTING PILOT PROJECTS. AND THEN IN PHASE II, THEY COULD DEMONSTRATE HOW EFFECTIVELY WERE THOSE SPECIALIZATIONS UTILIZED BY THE OTHER FACILITIES IN THE NETWORKS?

WITH RESPECT TO THE WORKFORCE DEVELOPMENT, IN PHASE I THE AWARDEES MAY DEMONSTRATE ENROLLMENT OF THE FIRST TRAINEE COHORTS FOR BOTH THE TECHNICAL AND LEADERSHIP TRAINING PROGRAMS. AND THEN IN PHASE II, THEY COULD DEMONSTRATE SUCCESSFUL ENROLLMENT IN TRAINING PROGRAMS AS WELL AS THE SUCCESS RATE OF TRAINEE JOB PLACEMENT.

AND ONE THING I SHOULD NOTE AS I'VE BEEN TALKING ABOUT THESE ACTIVITIES AND POTENTIAL OUTCOME

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METRICS IS THAT THE FUNDING IN THESE AWARDS WILL BE TO THE FACILITIES AROUND OPERATIONAL ENHANCEMENTS, BUT THE ACTUAL PROJECTS THAT THEY'RE SUPPORTING FOR CELL AND GENE THERAPY MANUFACTURING, THE FUNDING FROM THOSE WOULD STILL FLOW FROM THE TRAN AND CLIN AWARDS AND WILL BE CONTROLLED BY THE SPONSORS THEMSELVES. SO THE ACTUAL PROJECT SUPPORT IS COMING FROM OUR PIPELINE PROGRAMS, BUT THIS FUNDING MECHANISM AND THE FUNDING HERE IS FOCUSED WITH OPERATIONAL ENHANCEMENTS BEING MADE AT THE FACILITIES AND IN THAT SENSE IS PRETTY ANALOGOUS TO THE ALPHA STEM CELL CLINICS FUNDING OPPORTUNITIES.

SO NEXT SLIDE PLEASE. SO ALL OF OUR CURRENT FUNDING OPPORTUNITIES ADDRESS DEI AS WELL AS KNOWLEDGE SHARING. SO I'M JUST GOING TO BRIEFLY WALK THROUGH BOTH OF THOSE COMPONENTS THAT ARE ADDRESSED IN THIS PARTICULAR CONCEPT PLAN.

WITH RESPECT TO DIVERSITY, EQUITY, AND INCLUSION, THE APPLICANTS MUST PROPOSE A PLAN TO DEMONSTRATE HOW THEIR TRAINING PROGRAMS IN PARTICULAR WILL ENSURE PARTICIPATION BY UNDERSERVED POPULATIONS AS WELL AS HOW THEIR PROJECT REPRESENTS DIVERSE AND INCLUSIVE PERSPECTIVES AND EXPERIENCES.

NEXT SLIDE PLEASE.

ON THE KNOWLEDGE SHARING SIDE, THE

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APPLICATIONS WILL INCLUDE KNOWLEDGE SHARING PLANS THAT DESCRIBE THE PLAN TO CAPTURE AND DISSEMINATE RELEVANT KNOW-HOW, OPERATIONAL DATA, PROCESSES, EXPERTISE AND GUIDANCE IN THE NETWORK. SO THIS IS ALL THE KNOWLEDGE SHARING COMPONENT WITHIN THE NETWORK ACROSS THE DIFFERENT PARTICIPANTS THAT WILL REALLY BE THE COLLABORATIVE GLUE OF THE CONCEPT PLAN.

SECOND IS TO DESCRIBE ANY KNOWLEDGE SHARING PLANS THAT ARE CRITICAL TO ACHIEVING THE AWARD OBJECTIVES.

AND, LASTLY, IS TO DESCRIBE HOW THEIR FACILITIES DATA MANAGEMENT PROCESSES WILL SUPPORT CIRM TRAN AND CLIN AWARDEES TO EXECUTE ON THEIR RESPECTIVE DATA MANAGEMENT AND SHARING PLANS WHICH ARE NOW REQUIRED FOR ALL TRAN AND CLIN AWARDS GOING FORWARD.

AND SO I MENTIONED THAT CIRM WILL COORDINATE A STEERING COMMITTEE. SO I'M GOING TO DESCRIBE IN THIS SLIDE SOME OF THE FUNCTIONS THAT THE STEERING COMMITTEE COULD POTENTIALLY DO AND THE NEXT SLIDE HOW THEY TIE INTO THE ACTIVITIES THEMSELVES.

SO CIRM WILL COORDINATE A STEERING COMMITTEE OF AWARDEES, CALIFORNIA INDUSTRY PARTNERS,

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AS WELL AS A ROTATING GROUP OF NATIONAL STAKEHOLDERS TO FACILITATE IDENTIFICATION AND ADOPTION OF STANDARDS, PROTOCOLS, AND BEST PRACTICES ACROSS THE NETWORK AND TO CREATE POTENTIAL CRITERIA FOR FACILITY ACCREDITATION. TO MITIGATE CAPACITY AND EXPERTISE GAPS ACROSS PARTICIPATING SITES. TO FACILITATE COLLABORATIVE PLANNING FOR PHASE II PROPOSALS BETWEEN THE ACADEMIC AND INDUSTRY PARTICIPANTS. TO DEVELOP SYSTEMS AND PROCESSES FOR SHARING INFORMATION AND RESOURCES BETWEEN NETWORK PARTICIPANTS. AND LASTLY, TO PROMOTE COLLABORATIVE DEVELOPMENT AND IMPLEMENTATION OF WORKFORCE TRAINING PROGRAMS.

ON THE NEXT SLIDE I'LL DESCRIBE HOW THE STEERING COMMITTEE MIGHT PLAY A ROLE ON THE ACTIVITIES I PREVIOUSLY DESCRIBED A FEW SLIDES AGO. SO WITH RESPECT TO DERISKING MANUFACTURING, BOTH COULD BE THE ROLE OF THE STEERING COMMITTEE. WITH RESPECT TO THE PHASE I AWARDS, THE STEERING COMMITTEE COULD IDENTIFY QUALITY STANDARDS FOR ACADEMIC GMP FACILITIES TO ADOPT. IT COULD ALSO DEFINE THE KNOWLEDGE SHARING PROCESSES THAT MAY BE REQUIRED BETWEEN THE FACILITIES TO HELP FACILITATE BEST PRACTICES SHARING.

ON THE PHASE II SIDE, THE STEERING

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COMMITTEE COULD APPLY THE QUALITY STANDARDS CONSISTENTLY ACROSS THE NETWORK. THEY COULD FACILITATE KNOWLEDGE SHARING WITHIN THE NETWORK THROUGH SYSTEMS AND PROCESSES THAT ALLOW FOR THAT. AND LASTLY, THEY COULD ACTIVELY TRIAGE PROJECTS BY EXPERTISE AND CAPACITY ACROSS THE NETWORK.

AND NOW THE LAST SLIDE, I'M GOING TO DESCRIBE THE AWARD INFORMATION. SOME OF THIS IS INFORMATION I PRESENTED PREVIOUSLY. SO THE OVERALL PROGRAM BUDGET IS $80 MILLION. PHASE I IS $20 MILLION, WHICH WOULD GO LIVE THIS YEAR IF IT'S APPROVED BY THE BOARD. AND THEN PHASE II WILL BE DOWN THE ROAD AND WOULD BE $60 MILLION.

THE AWARDS THEMSELVES WOULD HAVE CAPS OF $2 MILLION FOR PHASE I AND $5 MILLION FOR PHASE II. THE ALLOWABLE COSTS FOR THESE AWARDS INCLUDE DIRECT PROJECT COSTS AND DIRECT FACILITIES COSTS. THEY DON'T INCLUDE INDIRECT COST, WHICH IS CONSISTENT WITH OTHER INFRASTRUCTURE FUNDING OPPORTUNITIES. AND THEY WILL ALSO INCLUDE A COFUNDING COMPONENT WHICH WILL BE REQUIRED FOR BOTH PHASES OF AWARDS AT 20 PERCENT.

IN TERMS OF APPLICANTS, JUST REITERATING THE CALIFORNIA NONPROFIT GMP MANUFACTURING FACILITIES CAN APPLY, AND THEY MUST HAVE A TRACK

RECORD OF CELL AND GENE THERAPY PROJECT SUPPORT.

AND THAT'S THE END OF MY PRESENTATION. SO CIRM ASKS THE BOARD TO APPROVE THIS CONCEPT PLAN, AND I WOULD TAKE ANY QUESTIONS THAT YOU MAY HAVE.

CHAIRMAN GOLDSTEIN: OKAY. LET'S SEE IF I CAN GET IT RIGHT THIS TIME. IS THERE A MOTION TO APPROVE?

DR. HIGGINS: SO MOVED.

CHAIRMAN GOLDSTEIN: THAT WAS DAVID.

DR. MIASKOWSKI: SECOND.

MS. BONNEVILLE: THANK YOU.

CHAIRMAN GOLDSTEIN: GREAT. ART, YOU HAVE A QUESTION?

MR. TORRES: THANK YOU, SHYAM, FOR THAT EXCELLENT PRESENTATION. I JUST HAD A QUESTION. WHAT IS CONSIDERED A NONPROFIT GMP?

DR. PATEL: THAT'S A GOOD QUESTION. SO MOSTLY IT WOULD BE THE ACADEMIC FACILITIES, ACADEMIC INSTITUTIONS THAT HAVE GMP FACILITIES, THE ONES I LISTED ON THE SLIDE. SO THOSE WOULD BE UC'S, CITY OF HOPE, STANFORD, CEDARS-SINAI, AND SO ON.

MR. TORRES: SO WHY DID YOU EXCLUDE INDUSTRY?

DR. PATEL: SO THE REASON FOR THAT IS THAT THE MAJORITY OF OUR PROJECTS GO THROUGH THE ACADEMIC

GMP FACILITIES AT THE EARLY STAGES. AND SO HERE THE INTENT IS THAT IF WE START THEM OFF ON THE RIGHT TRACK IN THE FIRST PLACE, THAT THE LATE STAGE TRANSITION TO INDUSTRY PARTNERS COULD BE SMOOTHENED. IN ADDITION TO THAT, WE THOUGHT THAT WHERE THE FUNDING IS MOST CRITICAL IS FOR THE ACADEMIC PARTNERS, AND THEN THE INDUSTRY PARTNERS COULD BE ONES WHO ARE COLLABORATING, PROVIDING THEIR RESOURCES HERE, AND BEING THE EVENTUAL HOUSE FOR THOSE LATER STAGE PROJECTS.

MR. TORRES: THANK YOU VERY MUCH. THANK YOU, MR. CHAIRMAN.

CHAIRMAN GOLDSTEIN: OTHER QUESTIONS OR COMMENTS? I ACTUALLY HAVE A -- J.T., GO AHEAD. YOU HAVE YOUR HAND UP.

CHAIRMAN THOMAS: SHYAM, WHEN WAS THE MANUFACTURING WORKSHOP?

DR. PATEL: SO THE MANUFACTURING WORKSHOP -- AND I APOLOGIZE. ALL THE TIMING IS IN MY HEAD, BUT I BELIEVE IT WAS LAST YEAR OR COULD HAVE BEEN THE YEAR BEFORE.

MS. BONNEVILLE: NO. IT WAS LAST YEAR. IT WAS LAST YEAR, SHYAM.

CHAIRMAN THOMAS: EARLIER LAST YEAR. I JUST RAISE THIS JUST TO MAKE THE POINT THAT THE

THINKING ON THE MANUFACTURING PROCESS AND WHAT WE CAN DO TO BE A PLAYER IN THAT HAS INVOLVED A TREMENDOUS AMOUNT OF WORK OVER MANY, MANY MONTHS. JUST THE PLANNING FOR THE MANUFACTURING WORKSHOP AND GETTING THE ATTENDEES AND EVERYTHING THAT WENT INTO THAT WAS A HUGE AMOUNT OF WORK. AND ALL THAT'S COME SUBSEQUENTLY WAS A FUNCTION OF THE LESSONS THAT WERE DERIVED FROM THAT WORKSHOP AND ULTIMATELY CULMINATES IN THIS CONCEPT PLAN, WHICH AS YOU CAN SEE FROM ITS COMPLEXITY AND THOROUGHNESS HAS INVOLVED A HUGE AMOUNT OF WORK. SO I SAY ALL OF THIS JUST TO CONGRATULATE SHYAM AND ALL MEMBERS OF THE TEAM FOR PUTTING TOGETHER A FIRST-RATE CONCEPT PLAN THAT WILL DRAMATICALLY IMPROVE THE MANUFACTURING ENVIRONMENT IN CALIFORNIA AND AS A RESULT FOR PATIENTS EVERYWHERE. JUST A COMMENT TO THAT EFFECT. VERY WELL DONE.

CHAIRMAN GOLDSTEIN: OTHER QUESTIONS OR COMMENTS? SHYAM, I HAVE A MINOR SUGGESTION, WHICH IS YOU MIGHT WANT TO MAKE IT CLEAR THAT THIS IS NOT INCLUDING CHEMICAL SYNTHESIS OR ANTIBODY PRODUCTION, THAT IT'S LIMITED TO PRODUCTION OF CELLS AND PROBABLY VIRAL OR OTHER TYPES OF VECTORS.

DR. PATEL: THANK YOU, LARRY. AS ALWAYS, YOUR RECOMMENDATIONS ARE SPOT ON.

CHAIRMAN GOLDSTEIN: THANK YOU.

OTHER COMMENTS OR QUESTIONS? PUBLIC COMMENT? ANYBODY ON THE LINE, MARIA?

MS. BONNEVILLE: IF THERE'S ANY PUBLIC COMMENT, IF YOU COULD PLEASE RAISE YOUR HAND, AND THEN YOU HAVE THREE MINUTES TO SPEAK. I DO NOT SEE ANY PUBLIC COMMENT.

CHAIRMAN GOLDSTEIN: OKAY. HEARING NONE --

MS. BONNEVILLE: I'M SORRY. ZAC, YOU HAVE THREE MINUTES.

DR. GRODZINSKI: I'M NOT SO FAMILIAR WITH THESE PROCEDURES. I'M WONDERING WHO IS RESPONSIBLE FOR TRACKING THE OUTCOME METRICS?

DR. PATEL: THANK YOU. THAT'S A GOOD QUESTION. SO THESE WILL BE BUILT INTO THE AWARDS THEMSELVES. AND SO THE METRICS WILL BE -- SO CRITERIA WE ESTABLISH AS PART OF THE AWARDS WOULD BE TRACKED BY THE AWARDEES AND THEN EVALUATED BY THE CIRM SCIENCE OFFICERS.

DR. GRODZINSKI: THANK YOU.

MS. BONNEVILLE: LARRY, WE HAVE ONE MORE PERSON FOR PUBLIC COMMENT.

DR. SAREEN: THANK YOU, GUYS. THIS IS A GREAT CONCEPT PLAN. I HAVE A QUESTION REGARDING THE

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PHASE I PART OF THE PROPOSAL WHERE THERE IS SOME DESCRIPTION REGARDING SPECIALIZED OFFERINGS THAT ARE SORT OF SUPPOSED TO FUND POSSIBLY TECHNOLOGY DEVELOPMENT PLATFORMS LIKE CRISPR OR IPS CELLS OR AUTOMATION, ET CETERA. IS IT -- SO I ASSUME THIS IS SOMETHING THAT THE ACADEMIC GMP'S WILL BE DEVELOPING INDEPENDENTLY OF A CLIENT'S PROJECT OR A PARTICULAR FOR-PROFIT CLIENT OR NOT-FOR-PROFIT CLIENT THAT'S ALREADY ONGOING IN THE GMP FACILITY. CAN THEY LEVERAGE THAT TO BE PART OF THIS PROPOSAL, OR ARE THE TWO MUTUALLY EXCLUSIVE? IT WILL BE HELPFUL TO CLARIFY.

DR. PATEL: THANK YOU, DHRUV. GREAT QUESTION. WITH RESPECT TO THAT, SO IT COULD BE THAT YOU MIGHT HAVE TO DO SOME DEVELOPMENT INDEPENDENT OF WHAT IS BEING FUNDED THROUGH A PARTICULAR PROJECT. AND THEN YOU CAN DEMONSTRATE THAT YOU MADE THAT SPECIALIZATION WITH THAT PROJECT. SO IT DOESN'T SPECIFICALLY HAVE TO BE COMPLETELY INDEPENDENT, AND THEY COULD BE RELATED. AND THIS FUNDING MECHANISM COULD BE USED TO DO SOME OF THE DEVELOPMENT THAT YOU MIGHT WANT TO DO INDEPENDENTLY OF WHAT MIGHT BE CONTRACTED THROUGH THAT PROJECT.

DR. SAREEN: THANK YOU.

CHAIRMAN GOLDSTEIN: THANK YOU FOR THAT

COMMENT AND QUESTION. LET'S SEE. ANYBODY ELSE?
OKAY. IF NOT, THEN WE VOTE.

MS. BONNEVILLE: LOREN ALVING.

DR. ALVING: YES.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: YES.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: LARRY GOLDSTEIN.

CHAIRMAN GOLDSTEIN: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: KAROL WATSON.

DR. WATSON: YES.

MS. BONNEVILLE: KEITH YAMAMOTO.

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DR. YAMAMOTO: YES.

MS. BONNEVILLE: THE MOTION CARRIES.

CHAIRMAN GOLDSTEIN: OKAY. THANK YOU, EVERYBODY.

ANY FINAL COMMENTS OR QUESTIONS? WE HAVE PRETTY MUCH REACHED THE END OF OUR AGENDA. ANY OTHER PUBLIC COMMENT NOT RELATED TO THIS TOPIC? NOTHING GOING. OKAY. WITH THAT, I SUGGEST THAT WE ADJOURN. SEE YOU AT THE NEXT MEETING. THANK YOU ALL FOR YOUR TIME.

MS. BONNEVILLE: THANKS, EVERYONE.

(THE MEETING WAS THEN CONCLUDED AT 11:41 A.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JULY 22, 2022, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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